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PREMARKET NOTIFICATION

**Cordis Corporation
STABILIZER Marker Wire
WIZDOM Marker Wire**

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Catheter Guide Wire

Proprietary Name: Cordis STABILIZER Marker Wire Steerable Guidewire
Cordis WIZDOM Marker Wire Steerable Guidewire

II. Name of Predicate Devices

Cordis STABILIZER with Radiopaque Markers (K952067 and K953750)
Cordis WIZDOM with Radiopaque Markers (K953750)
Gore SMOOTHER II (K941269)
Rulers and Calipers

III. Classification

Catheter Guide Wire, Class II - 21 CFR 870.1330
74DQX - Cardiovascular

IV. Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Cordis STABILIZER Marker Wire Steerable Guidewire and Cordis WIZDOM Marker Wire Steerable Guidewire are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

Cordis Marker Wire Steerable Guidewires have a soft, flexible, highly radiopaque platinum/tungsten coil on the distal tip and radiopaque markers along the length of the guidewire. Guidewire length, diameter, distal tip configuration and radiopaque marker configuration are indicated on the product label. A steering/torquing device may be attached to aid in steering/torquing the guidewire.

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VI. Biocompatibility

All materials have been tested as specified by the 1986 Tripartite Biocompatibility Guidance or the FDA modified matrix of ISO-10993 (Blue Book Memorandum G95-1). All material demonstrated compatibility with biological tissue by meeting the acceptance requirements stipulated in the test protocols.

VII. Summary of Substantial Equivalence

The Cordis STABILIZER Marker Wire Steerable Guidewire and Cordis WIZDOM Marker Wire Steerable Guidewire are substantially equivalent* in product design, indications for use, and packaging to the currently marketed Cordis Marker Wires. They are substantially equivalent in indications for use (as a measurement tool) and product design (incorporation of marker bands) to the Gore Smoother II. The Cordis STABILIZER and WIZDOM Marker Wire Steerable Guidewires are also similar to various rulers and calipers which are routinely used as measurement tools.

* A statement of substantial equivalence to another product is required by 21CFR 807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977).